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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,174	06/27/2001	William M. Blackshear JR.		5327

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EXAMINER	
RINES, ROBERT D	
ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/894,174	BLACKSHEAR ET AL.	
	Examiner	Art Unit	
	R. DAVID RINES	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 10 June 2008. Claims 1-16 have been cancelled. Claim 17 has been added. Claim 17 is pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[2] Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The basis of this rejection is set forth in a test of whether the invention produces a useful, concrete, and tangible result.

Under the guidance of recent case law, the requirements of 35 U.S.C. 101 are met when "the practical application of the abstract idea produces a useful, concrete, and tangible result" (*State Street Bank & Trust Co. vs. Signature Financial Group, Inc.*, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998)).

Claim 17 recites a series of method steps including "comparing said collected patient data against a medically accepted set of disease specific criteria at the evaluating authority to classify patients as "potentially at risk" and those patients "not at risk" of developing complications of arterial occlusive disease", and "reassessing the referred patient at the vascular surgery facility...". Examiner has reviewed the enabling disclosure provided in Applicant's specification with regard to the "comparison", "assessment/reassessment", "evaluation", and "classification" steps and has determined that each of these steps are dependent on human (i.e., medical expert) subjective processing. Following each of these steps, the claimed method derives the subsequent steps based on the findings of the "assessment" and "evaluation" steps. More directly, for the claimed invention to produce the desired result, the subjective assessment of the evaluating individuals must be the same each time.

As the claimed invention would, in aggregate, serve to diagnose and treat an individual, Examiner submits that the claimed invention serves to produce a result that is both useful and tangible. However, in order for a method to produce a concrete result, the net functional result must be repeatable. As the net result of the invention as defined by claim 17 is subject to human judgment calls (termed as "assessment" "evaluations") which could direct the process in a number of different directions, the result of the claimed invention is not repeatable.

In light of the above, it is respectfully submitted that the claimed invention, although useful, does not have a concrete result, and thus fails to recite the practical application of an abstract idea to satisfy the requirements of 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[3] Claims 1-16 have been cancelled.

[4] Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield (United States Patent #6,699,193).

As per (newly added) Claim 17, Crutchfield et al. disclose a method for the management and treatment of patients at risk of complications of arterial occlusive disease comprising the steps of: examining a patient at a healthcare facility with lower extremity arterial occlusion disease (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39), collecting patient data including physically observable conditions of the patient's lower extremities and noninvasive arterial pressure and blood flow data (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39), recording the collected patient data (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting said collected patient data to an

evaluating authority (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), comparing said collected patient data against a medically accepted set of disease specific criteria at the evaluating authority to classify patients "potentially at risk" and those patients "not at risk" of developing complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 25-50), transmitting said preliminary classification to the healthcare facility (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), referring those patients classified as "potentially at risk" of arterial of arterial occlusive disease to an accredited laboratory for noninvasive vascular evaluation (Crutchfield et al.; col. 9, lines 14-52), evaluating those "potentially at risk" patients at the accredited laboratory against medically accepted criteria (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), recording the results of said noninvasive vascular evaluation at the accredited laboratory (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting said recorded results to the evaluating authority for final classification (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), classifying each patient at the evaluating authority against medically accepted criteria as "at risk" or "not at risk" of developing arterial occlusive disease (Crutchfield et al.; col. 9, lines 40-52 and col. 10, lines 6-20), transmitting said "at risk" or "not at risk" patient final classification to the healthcare facility (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), recording said "at risk" or "not at risk" patient final classification at the healthcare facility (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), referring patient having a final classification of "at risk" for critical ischemia with associated extremity lesions and patients with and patient with noninvasive evidence of severe ischemia to a

vascular surgery facility for vascular surgical assessment to determine whether revascularization is necessary (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), assessing such "at risk" patients against medically accepted criteria as "clinical indication for operation" or "no indication for operation" at the vascular surgery facility (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), electing revascularization and periodic management system evaluation at the healthcare facility or routing wound care and periodic revaluation at the healthcare facility by patients assessed as "clinical indication for operation" (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), monitoring patients assessed as “no indication for operation” by the healthcare facility with increased precautions to monitor for detection of any visible deterioration of the patient's lower extremities that would require reassessment (Crutchfield et al.; col. 19, lines 50-67) referring patient having ulcers, pain, or gangrene at the time of "no indication for operation" assessment for reassessment (Crutchfield et al.; col. 09, lines 50-67), referring patients classified as “no indication for operation” that develop ulcers, pair and/or gangrene to the vascular surgery facility for reassessment (Crutchfield et al.; col. 09, lines 50-67), reassessing the referred patient at the vascular surgery facility against medically accepted criteria as “no indication for operation" or “clinical indication for operation” (Crutchfield et al.; col. 19, lines 50-67 and col. 20, lines 21-40), transmitting the reassessment of “no indication for operation” or “clinical indication for operation” to the evaluating authority for reevaluation as “no indication for operation" or “clinical indication for operation” (Crutchfield et al.; col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting the reevaluation to the healthcare faculty with the appropriate medical procedure and regimen (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and

col. 17, lines 1-8), treating and monitoring patients classified as "not at risk", " at risk" and assessed as "no indication for operation" or "clinical indication for operation" at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient without limb ulcers routing care and precautions at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient with limb ulcers routine wound care at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient with limb ulcers periodic reevaluation by the evaluating authority (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), providing "at risk" patients assessed as "no indication for operation" or "operation not elected by patient" and "clinical indication for operation" patient undergoing revascularization at the vascular surgery facility with intensive would care at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), and providing periodic reevaluations of "at risk" patient assessed as "no indication for operation" or "operation not elected by patient" with increased precautions at the healthcare facility (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67).

While Crutchfield et al., does not exemplify precisely the patient diagnosis and treatment scenario presented by claim 17 as presently amended, Crutchfield provides the functionality required to enable each of the "assessment" "reassessment" and "treatment" steps defined by claim 17 including the transmission of data and the referral of patients presenting a particular set of symptoms for appropriate treatment. Accordingly, a medical institution and associated staff practicing the Crutchfield et al. invention in the treatment of individuals with vascular disease

would achieve the method defined by claim 17 as a result of user selections (i.e., user choices) made during the course of practicing medicine (i.e., diagnosing and treating patients for vascular disease).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the system and method of Crutchfield et al. to accomplish the method steps defined by claim 17. One of ordinary skill in the art would have been motivated to do so by the desire to assess the vascular health of a patient in order to assess the effects of treatments, risk factors and substances, including therapeutic substances, on blood vessels by measuring various parameters of blood flow in one or more vessels and analyzing the results in a defined manner (Crutchfield et al.; col. 1, lines 25-30).

Response to Amendment/Declaration

[5] The declaration filed on 10 June 2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Crutchfield et al. (United States Patent #6,699,193) reference.

The evidence submitted is insufficient to establish either conception or a reduction to practice of the invention in this country of a NAFTA or WTO member country prior to the effective date of the Crutchfield et al. reference. Applicant's declaration consists of a "Letter of Agreement" between HealthHelp, Inc. and Tri-Med Management, Inc. The letter includes a general working arrangement between the two parties with regard to a joint interest designated as the Beverly Nursing Homes. The letter fails to include substantive evidence of the existence of the claimed invention directed to "classification and management system for patients with lower extremity arterial occlusive disease..." at the time of the "Letter of Agreement".

Conclusion

[6] Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. DAVID RINES whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Luke Gilligan can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. DAVID RINES/
Examiner, Art Unit 3626
6/19/2008

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626